# EFFECT OF ULTRASOUND CAVITATION VERSUS PHOSPHATIDYLCHOLINE IONTOPHORESIS ON CENTRAL OBESITY IN HYPERTENSIVE WOMEN

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# Abstract

Background/aim: Central obesity (CO) confers a great threat on the cardio-metabolic health of population. Central obesity is directly matched with increased visceral abdominal fat and it is also matched with endothelial dysfunction, insulin resistance, hypercholesterolemia, and cancer. Purpose of the study: This study was designed to compare between the effect of ultrasound cavitation and phosphatidylcholine iontophoresis on central obesity in hypertensive women. Material and methods: It is a randomized controlled trial performed on 40 hypertensive centrally obese females divided into two equal groups. Group (A) consisted of 20 females received ultrasound cavitation, Group (B) consisted of 20 females received phosphatidylcholine iontophoresis. The primary outcome measures were waist circumference, visceral fat range, systolic and diastolic blood pressure. Results: the results showed that there was statistically significant improvement in central obesity and hypertension in Group A but there was statistically significant improvement in central obesity but non-significant improvement in hypertension in Group B. Improvement in Group A is more significant than in Group B regarding the percent of decline in WC, VFR and DBP. Conclusion: there was improvement in central obesity and blood pressure in women after applying ultrasound cavitation and phosphatidylcholine iontophoresis with better results in ultrasound cavitation than phosphatidylcholine iontophoresis. Keywords: central obesity, ultrasound cavitation, iontophoresis, hypertension.

## Introduction

Central obesity is when high amount of abdominal fat around the stomach and abdomen has built up to the extent that it is likely to possess a negative impact on health. There is a high correlation between central obesity and cardiovascular disorder.<sup>1</sup>

The first cause of overweight is net energy imbalance, the organism uses more calories than it expends wastes, or discards through elimination. Some studies show that central adiposity, together with lipid deregulation and reduced insulin sensitivity, is matched to the excessive consumption of fructose. Higher meat consumption has also been positively associated with higher weight gain, and especially abdominal obesity. Other environmental factors, like maternal smoking, estrogenic compounds in food, and endocrine-disrupting chemicals are important too.<sup>2</sup>

Abdominal obesity (AO) is an independent and modifiable cardiovascular risk factor associated with a greater occurrence of coronary artery disease, left ventricular (LV) dysfunction and heart failure.<sup>3-5</sup> Obesity and arterial hypertension (AH) are directly related and their coexistence leads to the harmful impairment of cardiovascular structure and function.<sup>3,6,7</sup>

These cardiovascular changes in obese hypertensive patients can interfere, leading tonumerous hemodynamic constellations. This multifaceted interference becomes even more complicated in view of the results that patients with AO may present different hemodynamic patterns than those with overall obesity. AO correlates with higher metabolic activity strongly associated with the raised activity of the sympathetic nervous system and the renin—angiotensin—aldosterone system, also as altered endothelial dysfunction and hyperinsulinemia. As a result, hypertension with android obesity present higher arterial stiffness and impaired LV performance. It is concluded that AO may be foundwithin the models assessing cardiovascular risk as an independent variable.

Abdominal fats are formed of various distinct anatomic depots: Subcutaneous fat, which can be divided into anterior and posterior or superficial and deep layers, and intra-abdominal fat, thatcan be divided into intra-peritoneal and retroperitoneal sites. Intraperitoneal fat, also referred as visceral fat.<sup>18</sup>

Abdominally obese individuals are defined as those that have an increased waist circumference. Recent guidelines indicate a threshold of 102cm (40 inches) for males and 88 cm (35 inches) for females. Recent epidemiological surveys have indicated that abdominal obesity can be a better predictor of cardiovascular disorder than weight or BMI. 19

Phosphatidylcholine is a phospholipid taken from soybean lecithin that can be found in the cell membranes, actively sharing in the structure and transport among the cells.<sup>20</sup>

Phosphatidylcholine (PC) is a polar lipid molecule which is a naturally existed, integral component of all cell membranes, keeping the cells to have higher fluidity and strength. PC is a source of choline, a basic nutrient for liver function in addition to being a precursor of the neurotransmitter acetylcholine. Dietary sources of PC include soy lecithin. <sup>21</sup>

PC is a bile component and is responsible for lipid emulsification from the diet. PC is widely utilized in prophylaxis and management of embolism. It's also been knownto scale backthe systemic levels of cholesterol and triglycerides.<sup>22</sup>

Iontophoresis is a process that utilizes bipolar electric fields to propel molecules through intact skin toward the underlying tissue.  $^{23}$ 

The side effects following injection lipolysis are swelling, reddening, bruising, slight circulatory problems and increased stools in the first days after the injections. The side effects like

severe allergies and necrosis haven'thappened after treatments keep with the standards lay down by Network and will by now become apparent after not less than 60.000 documented treatments.<sup>24</sup>

Iontophoresis is an attractive way of drug delivery for the practitioners due tolower ionic concentrations required for its effectiveness, and since of its non-invasive nature.<sup>25</sup>

iontophoresis, whichmakes the movement of ions easierthrough a membrane under the effect of small electrical potential difference (0.5 mA/cm2 or less)applied externally, is one among the foremost promising new drug delivery system, which has proved to reinforce the skin penetration and therefore the release rate of a number of drugs having poor absorption/permeation profile through the skin. It is a localized, non-invasive, appropriate and fastway of moving water soluble, ionized drugsinside the skin. <sup>26</sup>

Iontophoresis had FDA approval in the 1970's. The utilization of this modality is rising in human physiotherapy and orthopedic medicine for the treatment of injury, arthritis, and over-use syndromes. Annually over 4 million people successfully receive drugs delivered by iontophoresis. <sup>25</sup>

# Aim of the study:

To determine the effect of the ultrasound cavitation and phosphatidylcholine iontophoresis on central obesity in hypertensive women.

# **Design of the study:**

Randomized control study design was used. 40 females with central obesity and essential hypertension were voluntary participated and randomly assigned into two groups with twenty subjects in each group. Patients with Cancer, renal failure, hemiplegia, Parkinsonism, fractures of extremities and respiratory diseases, Patient with secondary hypertension, left ventricular hypertrophy, Recent myocardial infarction, Three or more risk factors of CVD, Patients using more than one antihypertensive drugs Were excluded from the study

#### Method:

**Subjects:**Forty females with Central Obesity aging from 40-50 years old. They were selected from Beni Suef specialized Hospital, Beni Suef-Egypt. All subjects were investigated and diagnosed by internal medicine doctor. They received this treatment program between August and November 2020 and randomly assigned into two equal groups, group (A), and group (B).

- •Group (A): It included 20 females who received Ultrasound Cavitation treatment program for 30 days (8 sessions/patient).
- •Group (B): It included 20 females who received phosphatidylcholine iontophoresis treatment program for 30 days (four session/patient).

This study was performed under the ethical committee No: P.T.REC/012/001911, Beni Suef specialized Hospital, Beni Suef-Egypt.

# **Inclusion criteria:**

All patients were diagnosed clinically with central obesity as waist circumference > 88cm and BMI between 25and 35 kg/m2. And with essential hypertension (systolic BP 140-179mmhg & diastolic BP 90-109)

## **Exclusion criteria:**

Patients with these diseases were excluded from the study: Cancer, renal failure patients, hemiplegia, parkinsonism, fractures of extremities and respiratory diseases, We excluded diagnosed Patient with secondary hypertension, left ventricular hypertrophy , Recent myocardial infarction, Three or more risk factors of CVD, Patients using more than one antihypertensive drug.

## **Evaluation:**

All participants were assessed by a physician to select eligible subjects. Before inclusion in this study, a complete medical history and drug history were used for the patients. All tests were performed before the sessions (pre-) and after (post-) sessions period for each participant including Body Mass Index (BMI), Waist Circumference (WC), Visceral Fat Range (VFR), systolic and diastolic blood pressure (SBP) & (DBP). To control the acute effects of Ultrasound Cavitation and phosphatidylcholin iontophoresis on central obesity, all final results was measured at one month after the starting of the treatment sessions.

- Waist Circumference (WC): Measured by tap measurement at the mid abdominal level (umbilical level).
- Visceral fat range: Measured by Tanita device (made in Japan) is advanced bioelectric impedance analysis.
- Systolic and diastolic blood pressure: assessed by mercury sphygmomanometer (made in Japan)

# **Treatment procedures:**

- 1. Ultrasound cavitation: Lipocavi K800 (made in Korea) Medical cavitation was used in this study, all patients in group A were treated using ultrasound cavitation as follow: Patients lies in supine position with the right and left side free, cavitation hand piece applied at the abdomen after putting ultrasonic gel needed (medium), the device frequency sited according to fat accumulation thickness (fat layers), circular and regular movements of the hand piece over the treatment site applied, the duration of the treatment session was 20 minutes and each patient received 8 sessions with 3 days intervals between each one (2 sessions/week).
- 2.Phosphatidylcholine iontophoresis: Iontophoresis delivery unit (Dynatron IBOX) apparatus (made in USA) and Phosphatidylcholine lipolytic solution were used in this study. All patients in group B were treated as follow: The subject was lying in a comfortable and secure position, the phosphatidylcholine was applied under a wet cellulose sponge, which covers the electrode. And then secure the electrodes in position with soft rubber bandages. Fifteen to twenty minutes of treatment was usually sufficient at 5 mA. If it is necessary to decrease the intensity, an additional 5 or 10 minutes is indicated. The current intensity and treatment time used are up to maximum 0.5mA/cm2 for 20 min. the program was thirty days in which four sessions with ten days in between.

# **Statistical Analysis:**

A statistical package program was used to evaluate the data obtained from the study. Descriptive statistical methods (mean, median, and standard deviation) were utilized in the evaluation of research data as well as the Kolmogorov–Smirnov distribution test for evaluating normal distribution. In comparing quantitative data, the unpaired samples t-test was utilized in intergroup comparison of parameters. The Paired samples t-test was done for intragroup

comparisons. The results were computed at the 95% confidence interval, P < 0.05 significance level and P < 0.01 advanced significance level.

# **Results:**

Forty centrally obese and hypertensive females on stable pharmacological treatment were voluntary participated and randomly assigned into two groups with twenty patients in each group. No study participant left the study project for any reason. No side effects or complications were observed during the treatment.

Table 1 showed that the data was well matched regarding all baseline characteristics. There was no statistically significant difference between the two groups regarding the distribution of their age and BMI, WC, VFR, SBP, and DBP (P-value>0.05).

Table (1) Baseline characteristics among the studied groups:

Characteristics (Mean± SD)	GroupA (No=20)	Group B (No=20)	P-value
Age	34.6±3.3	34.8±3	0.882
BMI	31.2±2.2	32.3±2.5	0.135
WC	104.9±10.3	104.5±10.6	0.916
VFR	34.7±5.1	34.6±4.9	0.975
SBP	154.8±11.2	154.3±12.2	0.893
DBP	99±5	98.8±5.6	0.883

The average age was  $34.6\pm3.3$  years in group (A) and  $34.8\pm3$  years in group (B). The mean (BMI) of group (A) was  $31.2\pm2.2$  kg/m2 while in group (B) was  $32.3\pm2.5$  kg/m2. The mean WC of group (A) was  $104.9\pm10.3$  cm while in group (B) was  $104.5\pm10.6$  cm. The mean (VFR) of group (A) was  $34.7\pm5.1$  while in group (B) was  $34.6\pm4.9$ . The mean (SBP) of group (A) was  $154.8\pm11.2$  mmHg while in group (B) was  $154.3\pm12.2$  mmHg. The mean (DBP) of group (A) was  $99\pm5$  mmHg while in group (B) was  $98.8\pm5.6$  mmHg. Table 1

The decrease in WC in group (A) at the end of the treatment was statistically significant when compared with the baseline (P<0.001). The decrease in WC in group (B) at the end of the treatment was statistically significant too in comparison to the baseline (P<0.001). The percent of decline of WC in group (A) was higher than in group (B) with statistically significant difference between the two groups (P<0.001). Table 2

Table (2): comparison between pre and post treatment in both groups regarding waist circumference

WC	Pre-treatment	Post-treatment	P value*
Group A	104.9±10.3	99.7±11.4	0.001 S
Group B	104.5±10.6	100.9±10.3	0.001 S
P value**	0.916 NS	0.717 NS	

The decrease in VFR in group (A) at the end of the treatment was statistically significant as compared with the baseline (P<0.001). The decrease in VFR in group (B) at the end of the treatment was statistically significant too in comparison to the baseline (P<0.001). The percent of decline of

WC in group (A) was higher than in group (B) with statistically significant difference between the two groups (P<0.001). Table 3

Table (3): comparison between pre and post treatment in both groups regarding visceral fat range

VFR	Pre-treatment	Post-treatment	P value*
Group A	34.7±5.1	28.95±4.3	0.001 S
Group B	$34.6 \pm 4.9$	31.6±4.4	0.001 S
P value**	0.975 NS	0.066 NS	

The decrease in SBP in group (A) at the end of the treatment was statistically significant as compared with the baseline (P<0.001). While the decrease in SBP in group (B) at the end of the treatment was not statistically significant in comparison to the baseline (P=0.238). In spite of non-significant statistically difference in percent of decline of the SBP between the two groups (P=0.165), there is still a clinical significance of the higher percentage of change in group (A). Table 4

Table (4): comparison between pre and post treatment in both groups regarding systolic blood pressure

SBP	Pre-treatment	Post-treatment	P value*
Group A	154.8±11.2	143.5±8.4	0.001 S
Group B	154.3±12.2	149.8±9.9	0.238 NS
P value**	0.893 NS	0.072 NS	

The decrease in DBP in group (A) at the end of the treatment was statistically significant as compared with the baseline (P<0.001). While the decrease in DBP in group (B) at the end of the treatment was not statistically significant in comparison to the baseline (P=0.052). The percent of decline of DBP in group (A) was higher than in group (B) with statistically significant difference between the two groups (P=0.038). Table 5

Table (5): comparison between pre and post treatment in both groups regarding diastolic blood pressure

DBP	Pre-treatment	Post-treatment	P value*
Group A	99±5	91±3.1	0.001 S
Group B	98.8±5.6	94±5	0.051
P value**	0.883	0.029	

In spite of the non-significant statistical difference of the percent of decrease of the SBP between the two groups, there is still a clinical significance of the higher percent of change in group A. Figure 1

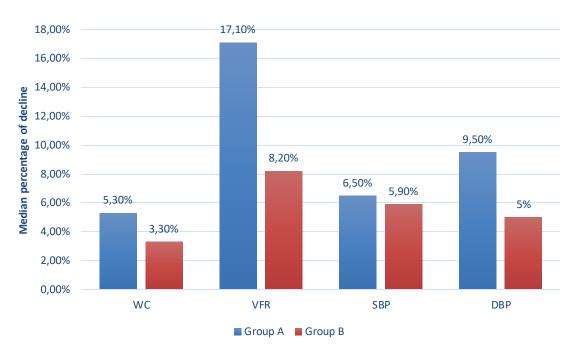


Figure 1 Median percentage of declines of waist circumference, visceral fat range, systolic and diastolic blood pressure in both groups

# **Discussion:**

Our clinical study showed that both ultrasound cavitation and Phosphatidylcholine iontophoresis systems are safe and effective for body contouring and for decreasing central obesity. Both significantly reduced excess abdominal adipose tissue, as reflected by the decrease in participants' waist circumference and visceral fat range measurements. Systolic and diastolic blood pressure was significantly reduced in group (A) using ultrasound cavitation but with no significant reduction in group (B) using phosphstidylcholine iontophoresis. However, there was significant change in the percent of decline in DBP. This reduction in abdominal fat could not be attributed to the loss of bodyweight because there was no significant distinction between the participants of the two groups in weight loss towards the end of the treatment.

In the present study the utilization of ultrasound cavitation for one month reduced the abdominal circumference by approximately 5.2 cm and reduced the VFR by approximately 4.7. The utilisation of phosphatidylcholine iontophoresis after one month reduced the abdominal circumference by approximately 3.6 cm and reduced the VFR by approximately 3. Also, the utilisation of ultrasound cavitation for one month reduced SBP and DBP by approximately 11.3 mmhg and 8 mmhg respectively. And the utilization of phosphatidylcholine iontophoresis for one month reduced SBP and DBP by approximately 4.5 mmhg and 4.8 mmhg respectively.

To the best of our knowledge, no previous studies have compared ultrasound cavitation and Phosphatidylcholine iontophoresis in participants with localized abdominal adiposity. Rather, the previous studies investigated the effect of either ultrasound cavitation only or Phosphatidylcholine iontophoresis only, without comparing techniques.

The results were consistent with the results achieved by Chong-Do and David who have stated that WHR was directly correlated with a greater prevalence of coronary artery calcification. This association persisted following additional adjustment for systolic blood pressure, fasting insulin concentrations, diabetes, and antihypertensive drug uyilization but became non-significant after additional adjustment for blood lipids. They also stated that abdominal obesity measured by waist

## **European Journal of Molecular & Clinical Medicine**

# ISSN 2515-8260 Volume 08, Issue 03, 2021

circumference or waist hip ratio is associated with early atherosclerosis as measured by the presence of coronary artery calcification in young adults. <sup>27</sup>

The results was also in the same line with Soojinwho argued thatInsulin resistance is increased by abdominal obesity and therefore the blood sugar level is related to the amount of the abdominal subcutaneous adiposity. <sup>28</sup>

Regarding the effect of cavitation, the results of this study agree those of with Savoia and colleagues, who showed that ultrasound cavitation is safe and effective for body contouring by decreasing abdominal fats within the treated area.<sup>29</sup> Savoia and colleagues recorded a reduce in waist circumference by almost 6.2 cm following treatment for 2 months. Additionally, Fatemi reported a reduce of 4–5 cm in waist circumference after ultrasound cavitation by the reduction of fat deposits.<sup>30</sup> Fatemi and Kane recorded a reduction in waist circumference by an average of 4.6 cm when utilizing ultrasound cavitation on subcutaneous fat.<sup>31</sup> Additionally, Saedi and Kaminer observed a reduce in abdominal circumference approximately 2 cm after using a single session of ultrasound cavitation.<sup>32</sup>

Furthermore, the results of this study support the results of Ascher, who reported that ultrasound cavitation is a compelling noninvasive technique for fat reduction and body contouring, which was demonstrated by a reduction of 3.58 cm in waist circumference following the treatment. Moreover, Teitelbaum and colleagues found an average reduction in waist circumference of 2 cm after a single treatment of cavitation. And Moreno-Moraga and colleagues reported an average of 3.95 cm waist circumferencedecreasefollowing ultrasound cavitation. Also, Shek and colleagues reported a 2.1 cm decrease in waist circumference in Chinese following 12 weeks of treatment by high intensity focused ultrasound.

Moreover, Tonucci and colleagues reported decrease of 1.5, 2.1, and 1.9 cm in the waist, abdominal and umbilical circumferences, respectively, after five sessions of low-frequency, low-intensity ultrasonic.<sup>37</sup> On the opposite hand, Shek and colleagues claimed that focused ultrasound is not effective for non-invasive body contouring among southern Asians.<sup>38</sup> The difference in results may be due to the variations of body size between southern Asians and our participants, in whom the treated area is larger than that of the southern Asians that produced more fat reduction.

Ultrasonic waves generate compression cycles that exert positive pressure, and expansion cycles that exert negative pressure. This pushing and pulling effect can crack the fat cells. Ultrasonic energy within the deeper fat layers can prompt cavities in the fat and theoretically reduce the overall thickness of the adipose layer. The mechanical acoustic effects of ultrasound cavitation caused selective fat cell disruption without causing injury to skin, vessels, nerves or connective tissue. 35,39,40

regarding the impact of phosphatidylcholin iontophoresis, these results came in agreement with the study of Rittes by injection of phosphatidylcholine into the adipose tissue. Pre and post treatment photos were captured for technical planning and analysis of the long term results. An obviousenhancement occurred altogether, with anobviousreduce of the fat deposits without recurrence over a 2 year follow-up period and no weight gain. The injection of phosphatidylcholine within the fat deposits can be a simple office procedure which will sometimes delay or even replace surgery and liposuction. <sup>41</sup>

Also, this study results agree with findings achieved by Bruke, and Denniswho Injected phosphatidylcholine as a non-surgical treatment in body contouring. The target of this study was to

approve the effect of injecting phosphatidylcholine in the decrease of localized fat deposits. 86 participants were included in the study. They received 1-3 treatments in localized fat deposits in different regions of the body using phosphatidylcholine. Following the treatment with phosphatidylcholine (250 mg / 5 ml), fat deposits show an average circumferential decrease per application of 2.70 cm. No patient showed irregularities, dimples or any serious side effect after treatment. Findings remained stable during the time of follow up. All patients showed obvious reductions of the fat deposits treated with phosphatidylcholine. Using the right technique, injecting phosphatidylcholine can be a safe and efficacious alternative to liposuction in patients refusing surgery. 42

The results of the present study support the findings of Weidmann who studied the effect of abdominal obesity on cardiovascular hemodynamics. The asymptomatic depression of the left ventricular diastolic and systolic function seems to be the earliest clinical feature of impaired Ventricular-vascular interactions. . One possible limitation of the present study is the lack of a laboratory investigation of lipid profiles or liver enzymes, which can be needed to complete the comparison between ultrasound and phosphatidylcholin iontophoresis regarding their safety. Another shortage is that more accurate measurements specific for measuring abdominal subcutaneous tissues thickness were not used, like ultrasonography.<sup>8</sup>

Further studies are required to compare between other non-invasive procedures for localized fat reduction to determine the best methodology through using lipid profile or liver enzymes investigations.

# Conclusion

Ultrasound cavitation and phosphatidylcholin iontophoresis is effective, safe, and well tolerated non-invasive procedures for decreasing fat thickness in the abdominal region and lowering systolic and diastolic blood pressure with slight advantage in ultrasound cavitation.

# Acknowledgment

We would like to thank all the women who shared in this study as well as our family members who supported us and anyone who assisted in this work.

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# ISSN 2515-8260 Volume 08, Issue 03, 2021

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